April 13, 2022

Bend It Technologies Ltd.
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K203842
Trade/Device Name: Bendit21 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: March 16, 2022
Received: March 17, 2022

Dear Sheila Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203842

Device Name

Bendit®21 Microcatheter

Indications for Use *(Describe)*

The Bendit®21 Microcatheter is intended for use in accessing target locations in the peripheral, coronary, and neuro vasculature and can be used to deliver both diagnostic agents, such as contrast media, and therapeutic devices.

Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted per the requirements of 21 CFR 807.92.

A. Submitter:

Bend It Technologies Ltd.
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Petach Tikva 4951038, Israel
Contact: Simona Beilin-Nissan
Title: Vice President Clinical and Regulatory Affairs
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B. Date Prepared: April 13, 2022

C. Device Name and Classification Information:

Trade Name:	Bendit®21 Microcatheter
Common/Usual Name:	Steerable microcatheter
Classification Name:	Catheter, percutaneous, neurovasculature
Regulation:	21 CFR 870.1250
Product Code:	QJP
Secondary Product Code:	DQY
Review Panel:	Neurology
Class:	II

D. Predicate Device: Headway 21 Microcatheter, K093160
Reference Device: Bendit®2.7 Steerable Microcatheter, K200582

E. Device Description:

The Bendit21 Microcatheter is a steerable microcatheter with a steerable distal tip. The tip's deflection is controlled using the Steering Slider on the proximal Steering Handle. The tip can be rotated bi-directionally while deflected by turning the Torque Knob on the Steering Handle.

The total working length of the Bendit21 Microcatheter is 157 cm. It is comprised of two Nitinol hypo tubes that are welded together at their distal ends, with proprietary laser-cut patterns along the 36 cm distal section. The laser cuts give the Bendit21 Microcatheter its flexibility while maintaining the Nitinol torsional rigidity for a high torque response. The distal 12 mm section is steerable using the proximal Steering Handle. The device includes two radiopaque markers, one at the tip and a radiopaque band located 30 mm from the tip. The distal portion of the catheter shaft (75 cm) is covered with a hydrophilic coating.

Sliding the Steering Slider forward moves the hypo tubes so that the distal tip deflects. When the Steering Slider is released, the tip shape is locked. The Bendit21 lumen can accommodate compatible guidewires (≤ 0.018 "). A standard Luer lock port for attachment of accessories is located at the proximal end of the Steering Handle.

The Bendit21 Microcatheter is compatible with the following types of therapeutic devices:

- Embolization particles with maximum particle size of 500 μm
- Coils with maximum coil wire size of 0.018''
- Stents/Stent Retrievers/Flow Diverters

F. Indications for Use Statement:

The Bendit21 Microcatheter is intended for use in accessing target locations in the peripheral, coronary, and neuro vasculature and can be used to deliver both diagnostic agents, such as contrast media, and therapeutic devices.

Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.

G. Technical Comparison with Predicate Device

The table below provides a technological comparison between the proposed Bendit21 Microcatheter and the predicate device. The similarities and differences between the proposed and predicate devices are discussed following the table.

	Proposed Device Bendit®21 Microcatheter	**Predicate Device Headway 21 Microcatheter**	**Comparison**
510(k) #	K203842	K093160	Not applicable
Regulation	QJP, DQY (21 CFR 870.1250)	DQY (21 CFR 870.1250)	Same, new Product Code created for neurovascular use since predicate 510(k) clearance
Indications for use	The Bendit21 Microcatheter is intended for use in accessing target locations in the peripheral, coronary, and neuro vasculature and can be used to deliver both diagnostic agents, such as contrast media, and therapeutic	The Headway 21 Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and	Similar

	Proposed Device Bendit®21 Microcatheter	Predicate Device Headway21 Microcatheter	Comparison
	devices. Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.	therapeutic agents, such as occlusion coils.	
Description	A single lumen catheter designed to be introduced either with or without a steerable guidewire to access small, torturous vasculature. The bendable proximal section transitions to a flexible, steerable distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories.	A single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible, shapeable distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories.	Testing demonstrated that the differences do not raise new questions of safety and effectiveness.
Microcatheter components	• Flexible catheter shaft with PTFE inner liner and hydrophilic coating • Steerable deflecting distal tip • Steering handle • Luer at proximal end for attaching accessories (i.e., syringes for injecting liquids)	• Flexible catheter shaft with PTFE inner liner and hydrophilic coating • Shapeable distal tip • Luer at proximal end for attaching accessories (i.e., syringes for injecting liquids)	Performance testing of the steerable tip and steering handle of the subject device demonstrated that the differences do not raise new questions of safety and effectiveness.
Catheter OD	3.1 Fr (1.03 mm, 0.041”)	Proximal: 2.5 Fr (0.83 mm, 0.033”) Distal: 2.0 Fr (0.67 mm, 0.026”)	Testing demonstrated that the difference does not raise new questions of safety and effectiveness.

	Proposed Device Bendit®21 Microcatheter	Predicate Device Headway21 Microcatheter	Comparison
Catheter ID	0.53 mm, 0.021''	0.53 mm, 0.021”	Same
Catheter shaft length	157 cm	156 cm	Similar
Length of hydrophilic coating	Distal 75 cm	Distal 110 cm	Testing demonstrated that the difference does not raise new questions of safety and effectiveness.
# Lumens	Single	Single	Same
Radiopaque	Yes, two radiopaque markers	Yes, two radiopaque markers	Same
How provided	Sterile, single-use, disposable	Sterile, single-use, disposable	Same

H. Discussion of Similarities and Differences

Indications for Use Statement

Both the proposed and predicate devices are microcatheters that are intended for use in the peripheral, coronary, and neuro vasculature and can be used to deliver both diagnostic agents and therapeutic devices.

Technological Characteristics

The proposed and primary predicate devices are both flexible microcatheters with radiopaque, atraumatic tips, and a hydrophilic coating along the catheter shaft. The main difference between the proposed and predicate microcatheters is that the proposed device has a steerable tip that can be deflected and rotated (in-situ) using the proximal steering handle, whereas the predicate device has a shapeable tip and is not steerable. However, the reference device, the Bendit2.7 Steerable Microcatheter, has the same steering mechanism as the Bendit21 Microcatheter. The Bendit2.7 Steerable Microcatheter is 510(k) cleared for use in the peripheral vasculature.

I. Testing to Support Substantial Equivalence

In Vitro Bench Testing

The results of in vitro bench testing and animal testing support the substantial equivalence of the Bendit21 Steerable Microcatheter. Testing was conducted in accordance with ISO 10555-1:2013 “Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements” (including Amendment 1:2017), where applicable, and internal test methods. The table below provides a summary of the in vitro bench testing. All tests were conducted on both as manufactured (t=0) and accelerated

aged (t=18 months) devices except where noted (see asterisks). Sample sizes for all tests were established to demonstrate 95%/90% confidence/reliability in the test results.

Test Name	Test Method Summary	Results
Visual and Dimensional Inspections*	Visual inspections for extraneous matter, surface defects, sharp edges. Measurements of device dimensions, such as angles, lengths, diameters.	**Pass**. No visual evidence of foreign matter, surface defects or sharp edges. All measurements met the pre-defined acceptance criteria.
Kink Resistance	Microcatheter samples are wrapped around a series of mandrels with decreasing diameters, until kink is evident.	**Pass**. The microcatheter demonstrated kink resistance in accordance with the test acceptance criteria.
Simulated Use, including: • Pushability • Retractability • Torsional Strength (Rotatability)	Microcatheter samples are navigated to different anatomical locations within a tortuous model and evaluated for pushability, retractability and damage post testing. Measurements of forces at the proximal end that are required to cause movement at the distal end.	**Pass**. All samples were successfully navigated through the tortuous model without damage and met the pre-defined acceptance criteria for forces.
Peak Tensile Force Along the Catheter Shaft (including Tip Peak Tensile)	Measurement of the forces at each microcatheter junction needed to separate the microcatheter into two or more pieces.	**Pass**. Tensile force to break for all samples for all junctions met the pre-defined acceptance criteria.
Air Leakage*	Included generating a reduced pressure to the microcatheter, and verifying the device is air leak proof.	**Pass**. No evidence of air leakage.
Liquid Leakage*	Applying liquid pressure to the microcatheter, and verifying the device is liquid leak proof.	**Pass**. No evidence of liquid leakage.
Priming Volume*	Measurement of the microcatheter priming volume and verification that it does not exceed the calculated volume.	**Pass**. Priming volume for all samples met the pre-defined acceptance criteria.
Fatigue (Tip Deflection and Tip Rotation)	Testing for tip deflection and tip rotation both in a tortuous simulated pathway and a straight configuration.	**Pass**. All samples exceeded the pre-defined number of tip deflection and tip rotation cycles without damage in both test configurations.
Torque Strength (Torque to Failure)	Measurement of the number of rotation cycles required to cause microcatheter breakage/kink when the tip is restrained, both in a tortuous simulated pathway and a straight configuration.	**Pass**. All samples exceeded the minimum number of cycles set by the test acceptance criterion before failure.
Torque Transmission	Measurement of the proximal-to-distal rotational ratio, between the microcatheter handle and the distal tip.	**Pass**. All measurements met the pre-defined acceptance criteria.
Flow Rate*	Measurement of the microcatheter flow rate through a constant level tank based on amount of water collected during a pre-defined time period.	**Pass**. All measurements met the pre-defined acceptance criteria.

Test Name	Test Method Summary	Results
Pressure Injection Flow Rate	Evaluation of the ability of the microcatheter to withstand high dynamic pressures, before and after passage of a representative worst-case therapeutic device within the inner lumen.	**Pass**. All samples withstood the applied injection pressures under the conditions of the testing without damage.
Burst Pressure*	Measurement of the static pressure the microcatheter can withstand before and after passage of a representative worst-case therapeutic device within the inner lumen.	**Pass**. All samples withstood the applied static pressure under the conditions of the testing without damage.
Interventional Device Compatibility	Assessment of the compatibility of the microcatheter to deliver representative therapeutic devices within the inner lumen, in an anatomical tortuous model, in terms of delivery forces and visible damage.	**Pass**. All samples were able to deliver all therapeutic devices used in the testing using acceptable delivery force and without any visible damage to the microcatheter.
Tip Deflection Force	Measurement of the tip deflection force in an anatomical model.	**Pass**. All measurements met the predefined acceptance criteria.
Tip Flexibility*	Characterization of the forces that induce buckling deformation at different distances from the distal tip.	**Pass.** Tip flexibility was comparable to the predicate device.
Particulate Characterization	The light obscuration particle counting method of USP <788> was used to measure the total number of particulates generated during simulated use in a tortuous model before and after passage of a representative worst-case therapeutic device within the inner lumen.	**Pass.** Particulate generation was acceptable and comparable to the predicate device.
Coating Integrity	Visual inspection of microcatheter surface to identify the location and size of any coating voids before and after simulated use.	**Pass**. All samples demonstrated acceptable coating integrity before and after simulated use.
Coating Length	Measurement of microcatheter coating length.	**Pass**. The coating length for all samples met the pre-defined acceptance criteria.

*Tests with an asterisk were only conducted on “as manufactured” (t=0) devices because the attributes measured by these tests were either covered under other tests conducted to confirm device integrity after aging (t=18 months, accelerated aging) or determined to not be affected by aging.

Animal Testing

The safety and performance of the Bendit21 Microcatheter compared to the predicate Headway 21 Microcatheter was evaluated in a porcine vascular model. Interventionalists used both the Bendit21 and the predicate Headway 21 microcatheters on opposite sides of the same animal to navigate to targets in renal, intracranial, and coronary arteries of various sizes. Animals were terminated at approximately 2 or 28 days post-procedure. The study evaluated multiple passes of each catheter through the same vessels. Additionally, the deflection and rotation of the Bendit21 Microcatheter tip to reach the target was tested

to simulate worst-case clinical use conditions. Device safety was assessed based on the animal's overall clinical status, occurrence of vasospasm, vessel patency through angiography, gross pathology and histologic evaluation of targeted vessels and downstream organs. Usability was assessed using pre-defined criteria, including visibility, trackability, pushability, torqueability, retraction and ease of use. Test results demonstrate the substantial equivalence of the Bendit21 Microcatheter to the predicate Headway 21 Microcatheter.

Sterilization Validation

Ethylene oxide (EO) sterilization was validated to a Sterility Assurance Level (SAL) of 10^{-6} using the half-cycle, overkill method per ISO 11135:2014, 2nd edition, "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices."

Bacterial endotoxin testing conducted using the LAL Test per USP 40-NF35:2017 <85> "Bacterial Endotoxins Test" confirmed endotoxin levels below 2.15 endotoxin units (EU)/device. EO and Ethylene Chlorohydrin residuals were evaluated according to ISO 10993-7:2008 "Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals" and were below the limits specified in the standard.

Biocompatibility

The Bendit21 Microcatheter is an externally communicating device with limited duration (<24 hours) of contact with circulating blood. Per FDA guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"," September 2020, the following tests were conducted:

Test Standard and Study Name	Test Method Summary	Results
ISO 10993-5:2009 Cytotoxicity Study Using the ISO Elution Method	Cell viability was evaluated. If viability is reduced to <50%, the device has a cytotoxic potential.	Moderately cytotoxic; In addition, chemical characterization and toxicological risk assessment was conducted to support acceptable cytotoxicity.
ISO 10993-10:2010 ISO Guinea Pig Maximization Sensitization Test	Animals tested with the test extract should show no evidence of delayed dermal contact sensitization.	Non-sensitizer
ISO 10993-10:2010 ISO Intracutaneous Study in Rabbits	Animals tested with the test extract should exhibit similar edema and erythema scores as the negative control.	Non-irritant

Test Standard and Study Name	Test Method Summary	Results
ISO 10993-11:2017 ISO Acute Systemic Toxicity Study in Mice	No animals injected with test article show a significantly greater biological reaction than the animals treated with the control article.	No acute systemic toxicity
ISO 10993-11: 2017 USP <151>, Pyrogen Test USP Rabbit Pyrogen Study	Animals tested with test extract should not exhibit increase of body temperature by more than 0.5°C.	Non-pyrogenic
ISO 10993-4:2017 ASTM F756:2017 ASTM Hemolysis Study	Mean hemolytic index for the direct contact and indirect contact should be < 2%.	Non-hemolytic
ISO 10993-4:2017 SC5b-9 Complement Activation Assay	The SC5b-9 concentration of the test sample shall not be statistically higher than both the activated normal human serum and negative controls.	Non-activator of the complement system
ISO 10993-4:2017 Thrombogenicity GLP Non-Anticoagulated Venous Implant (NAVI) Study of Thrombosis in Canine Model	No significant thrombi/emboli formation in the test article and results are comparable between the test and control devices.	Non-thrombogenic

Package and Shelf-Life Validation Testing

The following package validation and shelf-life testing was completed, and all test results met the requirements of the associated standard or protocol:

- Transportation testing according to ASTM D4169-16, “Standard Practice for Performance Testing of Shipping Containers and Systems” after simulated environmental and shipping conditions.
- 18 month accelerated aging (AA) in accordance with ASTM F1980-16, “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.”
- Package integrity testing included the dye penetration test per ASTM F1929-15 and seal peel test per ASTM F88M/F88-15, at both t=0 and after AA t=18 months.
- Device integrity testing following AA t=18 months to confirm proper device operation following aging and simulated distribution conditioning (see the table of bench tests for testing summaries).

J. Conclusion

The Bendit21 Microcatheter has intended use similar to the predicate and technological characteristics similar to the predicate and reference devices. The differences do not raise new questions of safety and effectiveness. The performance data demonstrate that the device functions as intended. The information and testing presented in this 510(k) demonstrate that the Bendit21 Microcatheter is substantially equivalent to the Headway 21 Microcatheter for use in the peripheral, coronary, and neuro vasculature.